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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/736,151	12/15/2000	Ali Laayoun	104959	8406
25944	7590	03/11/2004	EXAMINER	
OLIFF & BERRIDGE, PLC			TUNG, JOYCE	
P.O. BOX 19928				
ALEXANDRIA, VA 22320			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/736,151	LAAYOUN ET AL.
	Examiner	Art Unit
	Joyce Tung	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 12/08/2003 AND 1/8/2004.  
 2a) This action is **FINAL**.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 2,3,5-25 and 27-39 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 16 is/are allowed.  
 6) Claim(s) 2-3, 5-15, 17-25 and 27-39 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

The finality of the final rejection mailed 8/8/2003 is withdrawn in light the new ground of rejections.

Following the entry of the amendment filed 12/8/2003 and 1/8/2004; the claims 2-3 and 5-25 and 26-39 are pending.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 2, 5-15, 17-25 and 27-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 5, 7, 16, 18, 22, 24, 26, and 30-33 of U.S. Patent No. 6376179 in view of Gong (5,512,430, issued April. 30, 1996).

The instant claims are drawn to a method of fragmenting and labeling at least one synthetic DNA, RNA or chimeric DNA-RNA polymer in that at least one DNA or RNA comprising one thiophosphate nucleotide. The method of the instant invention comprises chemical fragmentation of synthetic DNA, RNA or chimeric DNA-RNA polymer in the presence of multivalent metal cations to produce a plurality of fragment and attaching at least one label to the fragment with a labeling agent to produce a detectably labeled fragment. The method of

instant invention is done in a single reaction mixture. Claims 1-2, 5, 7, 16, 18, 22, 24, 26 and 30-33 of U.S. Patent No. 6/376,179 are also drawn to a method for labeling a synthetic or natural RNA involving fragmenting the RNA to produce a plurality of RNA fragments having freed terminal phosphates in the presence of metal cation as recited in claims 7, and 16 and chemical catalyst as recited in claims 5 and labeling a plurality of the fragment with labels recited in claims 24 at the terminal phosphates freed in the fragmenting step. The method of the patent can be done in one step. The differences of two inventions are that the method of the instant invention involves an additional step of treating said aqueous solution to decrease or eliminate unattached labeling agent and the treating step includes adding a chelating agent to the mixture after fragmentation and attaching steps. However, Gong discloses the use of nucleic acid to diagnose disease in which after the labeling step, EDTA was added to the labeling solution and the labeled probe was isolated with mini sephadex by spin column chromatography and collected (See column 7, lines 45-58). By doing so, the noise background is reduced and the method become more accurate and sensitive (See column 3, lines 48-51). Therefore, it would have prima facie obvious to eliminate unattached labeling agent and add a chelating agent after fragmenting and attaching steps in the instant invention.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 3 recites the limitation "said member" in claim 3. There is insufficient antecedent basis for this limitation in the claim.

***Allowable Subject Matter***

5. Claim 16 is allowable.
6. The following is a statement of reasons for the indication of allowable subject matter:

Concerning claim 16, no prior art has been found teaching or suggesting the method of fragmenting and labeling DNA or RNA in an *in vitro* nucleic acid amplification mixture.
7. U.S. patent NO. 5,981,734, issued Nov. 9, 1999 is made of record as reference of interests because the reference teaches fragmenting and labeling nucleic acid (See column 4, lines 15-29).

***Summary***

8. Claims 2-3, 5-15, 17-25 and 27-39 are not allowable.
9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

February 26, 2004



ETHAN WHISENANT  
PRIMARY EXAMINER